



Patent
Attorney's Docket No. 012627-025

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:)
Hans Konrad SCHACKERT *et al.*) Group Art Unit: 1634
Application No.: 09/936,738) Examiner: Ethan C. Whisenant
Filed: September 17, 2001) Confirmation No.: 8967
For: METHOD FOR IDENTIFYING)
ORGANISMS BY MEANS OF)
COMPARATIVE GENETIC)
ANALYSIS AND PRIMERS AND)
HYBRIDIZATION PROBES FOR)
CARRYING OUT THIS METHOD)

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RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This Response to Restriction Requirement is in complete response to the Official Action (Restriction Requirement) mailed on November 14, 2002 (Paper No. 14). This response is timely filed by the December 16, 2002 due date (December 14 and 15, 2002 were a Saturday and a Sunday, respectively).

Applicants hereby elect with traverse the claims of **Group I** (Claims 1-18 and 27-31), which are drawn to a method of identifying organisms by comparative genetic analysis.

Unity of invention is fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical

features. 37 C.F.R. § 1.475. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. *Id.*

Applicants submit that in contrast to Jensen *et al.* (U.S. Patent No. 5,753,467) and Rogan *et al.* (U.S. Patent No. 5,849,492), the present invention uses the highly conserved PTEN gene. The present invention describes highly conserved primer sequences in exons and introns of PTEN for amplification of homologous genes of PTEN in various animal species. In addition, the inventors used this approach based on the primers described to identify novel sequences of these animals. The inventors describe a new function and use of these primers and sequences, such as amplification of unknown sequences of various animal species. This approach is suitable for all methods available for DNA analysis and obtains data for taxonomic assignment of unknown species. Thus, it is not proper to consider each oligonucleotide primer as separate invention. They work together to identify and characterize various animal species. In fact, the whole PTEN gene (exons and introns) is highly conserved during evolution since it has important functions during embryogenesis and in the homeostasis of the adult organism which need the whole PTEN gene. Thus, it has to be considered in its function and degree of conservation as one unit and is in the sum of its exons highly conserved. Furthermore, the cDNA of this gene (the sum of its exons without introns) is be considered as unit. On the genomic level, it is often not possible to amplify all exons in one PCR in view of its size (PTEN/MMAC1 comprises 102,000 base pairs). Thus, the testing of the individual exons requires more than one PCR. Because the use of only one exon is not enough to determine the species of an animal, it is necessary to

test more than one exon, *i.e.* a combination of exons and introns (as recited in claims 10-14 and 32-37).

Furthermore, the cDNA is used in the present invention for animal species determination purposes. When creating a biochip all exons and the 5' and 3' untranslated region of the gene will be used and, in addition, may serve as internal controls. Thus, Applicants note that dividing the invention into the single exons and/or introns will destroy the approach of the invention, which is to make animal species identification. This species identification is only possible by combining the information obtained by analysis of several exons or introns. Thus, as the exons and introns of the present invention are used together to result in the claimed invention, Applicants submit that all of the claims share one technical feature, as required under the unity of invention requirement. If they did not share at least one technical feature, they would not be able to work together to achieve the claimed invention.

As Applicants have traversed the rejection, Applicants note for the record the following regarding the instant restriction requirement. Under M.P.E.P. § 803, a restriction is proper if the subject matter can be restricted into one of two or more claimed inventions, and these inventions are either independent (M.P.E.P. § 806.04) or distinct (M.P.E.P. § 806.05). However, the second element for a restriction requirement to be proper is that if the search and examination of an entire application can be made without serious burden, the examiner *must* examine it on the merits, even though it includes claims to independent and distinct inventions. Additionally, under M.P.E.P. § 816, "[t]he particular reasons relied on by the examiner for holding that the inventions as claimed are

either independent or distinct should be concisely stated. A mere statement of conclusion is inadequate." Applicants submit that a serious burden to examine both groups of claims has not been adduced.

Finally, if the Examiner will not rejoin all of the groups of claims, Applicants respectfully request the rejoinder of the claims of Group I with the claims of Group XIX (claims 46-47). These two Groups are closely related to each other and should not pursued in two different applications.

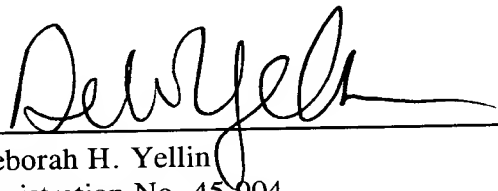
Accordingly, for at least all of the reasons set forth above, withdrawal of the requirement for restriction is requested and believed to be in order. Further and favorable consideration of all the claims of record on the merits is respectfully requested.

In the event that there are any questions relating to this Response to Restriction Requirement, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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